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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Rudolf FAHRIG et al.

Appl'n No. : 10/550,013

Filed : September 23, 2005

Group Art Unit: unknown

Examiner: unknown

For : USE OF 5-SUBSTITUTED NUCLEOSIDES FOR REINFORCING THE APOPTOTIC EFFECT OF CYTOSTATIC DRUGS

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
U.S. Patent and Trademark Office
Customer Service Window, Mail Stop AMENDMENT
Randolph Building
401 Dulany Street
Alexandria VA 22314

Sir:

In accordance with the duty of disclosure under 37 C.F.R. 1.56, 1.97, and 1.98, Applicant hereby brings the following information to the attention of the Examiner, which includes information cited and discussed in the specification, the International Search Report, the Written Opinion and the International Preliminary Examination Report issued in connection with counterpart International Application No. PCT EP 03/013008. Copies of the International Search Report (in English and German), the Written Opinion (in German) and the International Preliminary Examination Report (in German) were enclosed with the papers when entering the National Stage on September 23, 2005. Also enclosed is a copy of an English translation of the International Preliminary Examination Report dated June 29, 2005.

The Examiner is invited to review these materials to inspect the relevance indicated during international examination with respect to the documents cited therein.

U.S. 6,589,941 (and its family member WO 96/23506);

EP 0 806 956 B1;

WO 01/07088 A2 and A3;

WO 96/23506;

WO 02/067951 A2 and A3 (and family member U.S. Patent Publication 2004-0127454 A1, published July 1, 2004);

E. de Clercq, "Potential of Bromovinyldeoxyuridine in Anticancer Chemotherapy," Anticancer Research, vol. 6, no. 4, July 1986, pp. 549-556;

R. Fahrig et al., "Prevention of adriamycin-induced mdr1 gene amplification and expression in mouse leukemia cells by simultaneous treatment with the anti-recombinogen bromovinyldeoxyuridine," Anti-Cancer Drug Design (2000),15(5), pp. 307-312 (incorrectly dated 2001 in the International Search Report);

M. Iigo et al., "Effect of (E)-5-(2-bromovinyl)-2'-deoxyuridine on Life-Span and 5-Fluorouracil metabolism in Mice with Hepatic Metastases," Euro. J. Cancer, vol. 26, no. 10, 1990, pp. 1089-1092;

B. Degreve at al., "Selection of HSV-1 TK Gene-Transfected murine Mammary Carcinoma Cells Resistant to (E)-5-(2-bromovinyl)-2'-deoxyuridine (BVDU) and ganciclovir (GCV)" Gene Therapy (2000), 7(18), pp. 1543-52;

J. Balzarini, "Increased Sensitivity of Thymine Kinase Deficient (TK-) Tumor Cell Lines to the Cell Growth Inhibitory Effects of (E)-5-(2-bromovinyl)-2'-deoxyuridine (BVDU)

and Related Compounds," Anticancer Research, vol. 6, no. 5, 1986, pp. 1077-1084;

S. Pancheva, "Methotrexate Potentiates Anti-Herpes Simplex Virus Type 1 Activity of E-5-(2-bromovinyl)-2'-deoxyuridine," Acta virologica, vol. 39, no. 2, 1995, pp. 117-119;

J. Kerr et al., "Apoptosis: A Basic Biological Phenomenon with Wide-Ranging Implications in Tissue Kinetics," Br. J. Cancer, (1972) 26, pp. 239-257;

R. Fahrig et al., "Induction or suppression of SV40 amplification by genotoxic carcinogens, non-genotoxic carcinogens, or tumor promoters," Mutation Research 356 (1996) 217-224;

R. Fahrig, "Anti-recombinogenic and convertible co-mutagenic effects of (*E*)-5-(2-bromovinyl)-2'-deoxyuridine (BVDU) and other 5-substituted neucleoside analogs in *S. cerevisiae* MP1," Mutation Research 372 (1996) 133-39;

Hodnick et al., "Measurement of Dicumarol-Sensitive NADPH:(Menadione-Cytochrome c) Oxidoreductase Activity Results in an Artifactual Assay of DT-Diaphorase in Cell Sonicates," Anal. Biochem. 252(1), 1997, 165-168.

Applicants also bring to the attention of the Examiner the following commonly assigned co-pending application:

U.S. Patent Publication 2004-0127454 A1, published July 1, 2004.

In accordance with 37 C.F.R 1.98, copies of the U.S. patent and published U.S. patent application are not enclosed herewith. However, if any copies are needed, the Examiner is respectfully requested to contact the undersigned.

This Information Disclosure Statement includes a duly completed Form PTO-1449 listing all of the above-cited documents, and includes copies of the listed documents (other

than U.S. Patents and U.S. Patent Publications). The Examiner is accordingly requested to consider each of these documents, and to make them of record in this application by initialing in the appropriate spaces on the Form PTO-1449. Applicant respectfully requests that the Examiner include a copy of the initialed Form PTO-1449 with the next communication from the U.S. Patent and Trademark Office.

Because a first Office Action has not been received, it is believed that no fee should be necessary for consideration of this Information Disclosure Statement. However, if a fee is required for any reason, then this should be considered express authorization to charge any necessary fee for consideration of this Information Disclosure Statement to Deposit Account No. 19-0089.

Should there be any questions, the Examiner is invited to contact the undersigned at the below listed telephone number.

Respectfully submitted,
Rudolf FAHRIG et al.

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FORM PTO-1449	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No. P28506	Application No. 10/550,013
	INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	Applicant Rudolf FAHRIG et al.	
		Filing Date September 23, 2005	Group Unknown

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
		6 5 8 9 9 4 1	07/08/03	FAHRIG et al.			
	2004	0 1 2 7 4 5 4	07/01/04	FAHRIG et al.			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES	TRANSLATION NO
		0 8 0 6 9 5 6	08/28/02	E.P.O				
	01	/ 0 7 0 8 8	02/01/01	W.I.P.O				
	96	/ 2 3 5 0 6	08/08/96	W.I.P.O				
	02	/ 0 6 7 9 5 1	09/06/02	W.I.P.O				

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	1	E. de Clercq, "Potential of Bromovinyldeoxyuridine in Anticancer Chemotherapy," Anticancer Research, vol. 6, no. 4, July 1986, pp. 549-556.
	2	R. Fahrig et al., "Prevention of adriamycin-induced mdr1 gene amplification and expression in mouse leukemia cells by simultaneous treatment with the anti-recombinogen bromovinyldeoxyuridine," Anti-Cancer Drug Design (2000),15(5), pp. 307-312 (incorrectly dated 2001 in the International Search Report).
	3	M. Iigo et al., "Effect of (E)-5-(2-bromovinyl)-2'-deoxyuridine on Life-Span and 5-Fluorouracil metabolism in Mice with Hepatic Metastases," Euro. J. Cancer, vol. 26, no. 10, 1990, pp. 1089-1092.
	4	B. Degreve at al., "Selection of HSV-1 TK Gene-Transfected murine Mammary Carcinoma Cells Resistant to (E)-5-(2-bromovinyl)-2'-deoxyuridine (BVDU) and ganciclovir (GCV)" Gene Therapy (2000), 7(18), pp. 1543-52.
	5	J. Balzarini, "Increased Sensitivity of Thymine Kinase Deficient (TK-) Tumor Cell Lines to the Cell Growth Inhibitory Effects of (E)-5-(2-bromovinyl)-2'-deoxyuridine (BVDU) and Related Compounds," Anticancer Research, vol. 6, no. 5, 1986, pp. 1077-1084.
	6	S. Pancheva, "Methotrexate Potentiates Anti-Herpes Simplex Virus Type 1 Activity of E-5-(2-bromovinyl)-2'-deoxyuridine," Acta virologica, vol. 39, no. 2, 1995, pp. 117-119.
	7	J. Kerr et al., "Apoptosis: A Basic Biological Phenomenon with Wide-Ranging Implications in Tissue Kinetics," Br. J. Cancer, (1972) 26, pp. 239-257.
	8	R. Fahrig et al., "Induction or suppression of SV40 amplification by genotoxic carcinogens, non-genotoxic carcinogens, or tumor promoters," Mutation Research 356 (1996) 217-224.
	9	R. Fahrig, "Anti-recombinogenic and convertible co-mutagenic effects of (*E*)-5-(2-bromovinyl)-2'-deoxyuridine (BVDU) and other 5-substituted neucleoside analogs in *S. cerevisiae* MP1," Mutation Research 372 (1996) 133-39.
	10	Hodnick et al., "Measurement of Dicumarol-Sensitive NADPH:(Menadione-Cytochrome c) Oxidoreductase Activity Results in an Artifactual Assay of DT-Diaphorase in Cell Sonicates," Anal. Biochem. 252(1), 1997, 165-168.

EXAMINER	DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.